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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,386	05/10/2001	Steven L. Roberds	00133.US1	5508

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EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/852,386	Applicant(s) ROBERDS ET AL.	
	Examiner Michael Pak	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-116 is/are pending in the application.
- 4a) Of the above claim(s) 1-29, 36-73, 75-88 and 95-115 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-35, 74, 89-94 and 116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8-24-01</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's election with traverse of Group 150 in Paper filed March 5, 2004 is acknowledged. The traversal is on the ground(s) that there would not be serious burden on the examiner to examine also the Group 189 drawn to antibodies. This is not found persuasive because the groups are classified separately.

The requirement is still deemed proper and is therefore made FINAL.

Claims 30-35, 74, 89-94 and 116 drawn to SEQ ID NO:73 are examined below.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 30-35, 74, 89-94 and 116 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The claims are directed to a polypeptide which comprises a portion of ion-x and its homologue. The specification on page 5 disclose the asserted utility of using the protein for treat a number of diseases. However, there is no nexus between the claimed protein and the therapeutics for humans. The specification as filed does not disclose or provide evidence that points to a property of the claimed protein such that another non-asserted utility would be well established.. The polypeptide lacks substantial utility because further research to identify or reasonably confirm a "real

world” context of use is required. Thus, the asserted utility lacks substantial and specific utility because further research to identify or reasonably confirm a “real world” context of use is required. *Brenner V. Manson* 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966) stated that “Congress intended that no patents be granted on an chemical compound whose sole “utility” consists of its potential role as an object of use-testing ... a patent is not a hunting license.” *Brenner* further states that “It is not a reward for the search, but compensation for its successful conclusion.” Any utility of the nucleic acid encoding the protein or other specific asserted utility is directly dependent on the function of the protein. A circular assertion of utility is created where the utility of the protein is needed to break out the circular assertion of utility. The polypeptides do not substantial utility because the skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its functional nexus with human therapeutics. Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used. The disclosed use for the nucleic acid molecule of the claimed invention is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence claimed. The disclosed use directed to vectors and host cells do not have utility because the nucleic acid without utility is needed to practice the inventions.

Claims 30-35, 74, 89-94 and 116 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 30-35, 74, 89-94 and 116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30-35, 74, 89-94 and 116 recite or encompass SEQ ID NO: sequences which are not elected and which is confusing and ambiguous.

4. Claims 30, 32-35, 74, 89, 91-94 and 116 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 30, 32-35, 74, 89, 91-94 and 116 encompass an isolated polypeptide variants and fragments of proteins without functional limitations. However, the essential feature of the invention is the polypeptide channel subunit of SEQ ID NO:73, and one of skilled in the art cannot envision the full genus of molecules of the claimed

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polypeptide molecules. The claims encompass variants whose structure is not known or other variant proteins with different function from SEQ ID NO:73 taught in the specification. Claimed protein variants encompass a large genus of proteins or channels which are alleles or variants whose function has yet to be identified from different species of animal because the structure of the newly identified naturally occurring protein is not known. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification.

Priority

5. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 30-35, 74, 89-94 and 116 of this application for the reasons provided above. See MPEP 706.02.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 30, 32-35, 74, 89, 91-94 and 116 are rejected under 35 U.S.C. 102(b) as being anticipated by Meadows et al. (WO 99/37762).

Meadows et al. discloses a potassium channel comprising SEQ ID NO:2 which is 64.3% best local similarity to the claimed polypeptide of SEQ ID NO:73 (pages 2-3 and 19). Meadows et al. discloses a composition comprising the polypeptide with a carrier (page 17). Meadows et al. discloses a chimeric receptor comprising the polypeptide (page 2). Claims 30, 32-35, 74, 89, 91-94 and 116 encompass variants and is anticipated by the polypeptides of Meadows et al.

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7. Claims 30, 32-35, 74, 89, 91-94 and 116 are rejected under 35 U.S.C. 102(e) as being anticipated by Meadows et al. (US 6,242,217).

Meadows et al. discloses a potassium channel comprising SEQ ID NO:2 which is 64.3% best local similarity to the claimed polypeptide of SEQ ID NO:73 (columns 2, 4, 6 and 15-16). Meadows et al. discloses a composition comprising the polypeptide with a carrier (columns 10 and 14). Meadows et al. discloses a chimeric receptor comprising the polypeptide (columns 2). Claims 30, 32-35, 74, 89, 91-94 and 116 encompass variants and is anticipated by the polypeptides of Meadows et al.

8. Claims 30-35, 74, 89-94 and 116 are rejected under 35 U.S.C. 102(e) as being anticipated by Guegler et al. (WO 02/24748).

Guegler et al. discloses a potassium channel comprising SEQ ID NO:2 which is 100% identical to the claimed polypeptide of SEQ ID NO:73 (pages 6-7 and 15-24). Guegler et al. discloses a composition comprising the polypeptide with a carrier (page 21). Guegler et al. discloses a chimeric receptor comprising the polypeptide (page 15).

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:30 am - 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-0507.

Michael D. Pak

Michael Pak
Primary Examiner
Art Unit 1646
27 May 2004